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10/027,478	12/21/2001	Joshua Levy	HEMAC:58977	9947

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FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/027,478	Applicant(s) LEVY, JOSHUA	
	Examiner Ginny Portner	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending.

Information Disclosure Statement

1. The information disclosure statement filed June 6, 2002 has been considered.

2. It was noted that several of the citations were incomplete and lacked reference to the author, pages of the reference, volume and issue number and/or recited a website designation. In complete citations should be completed and resubmitted. The reference copies were considered prior to this action.

3. The disclosure should not contain any embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete any embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamers et al (EP 0739981A1) (1996).

6. **Please note**: In light of Applicant's definition, that includes the administration of neutralizing monoclonal antibodies (see Instant Specification page 6, paragraph 3) " the phrases "deriving a supply of plasma" and "processing the plasma derived therefrom" are being read to include blood that comprises lymphocytes present in peripheral blood from which the immunoglobulins, specifically IgG gamma globulins can be derived.

Hamers et al (EP 0739981A1) discloses the instantly claimed invention directed to a method of treatment of a patient infected with anthrax using passive hyper immune antibody therapy, the method comprising the steps of:

Deriving a supply of plasma from previously vaccinated (see page 3, lines 35-36: "an animal of the Camelid family previously immunized with a determined antigen; page 4, lines 52-55;) individuals (see page 2, lines 53-58; page 3, line 3: "secreted in blood of camelids" (individuals));

Processing the plasma derived therefrom to provide a preparation (see page 3, lines 35-51) of gamma globulins (see page 2, lines 41-52; page 5, lines 1-3 (IgG2 and IgG3)) with a high titer of neutralizing antibodies (see page 3, lines 20-21 "effective"; page 8, lines 1-3 "elicit neutralizing antibodies") to anthrax (page 5, lines 6-9 "Bacillus anthraces"; page 7, lines 1-6), the derived preparation being sterilized (filter sterilized through a filter (see page 9, line 5)) and impurity free; and

Administering the processed plasma preparation to the infected ("acute" infection, see page 11, lines 26-27) patient (see page 6, lines 54-57; see page 11 lines 14-54, especially lines 21, 40).

The reference anticipates the instantly claimed invention in light of Applicant's definition of the claimed invention including monoclonal antibodies; the antibodies being derived from a product in plasma, specifically lymphocytes.

7. Claims 1-6, 9,11-14 are rejected under 35 U.S.C. 102(e), effective filing date November 9, 2001) as being anticipated by Shiloach et al (PG Pub 2004/0076638A1, effective filing date November 9, 2001) .

Shiloach et al discloses the instantly claimed invention directed to a method of treatment of a patient infected with anthrax using passive hyper immune antibody therapy (see [0038] and claims 32-35), the method comprising the steps of:

Deriving a supply of plasma (see paragraph [0031]) from previously vaccinated (see paragraph [0032]) individuals (see paragraphs [0057] through [0061]);

Processing the plasma derived therefrom to provide a preparation (see [0061, line 2]) of gamma globulins (see [0061 "IgG, IgG1, IgG2, IgG3, IgG4"]) with a high titer (see [0032]) of neutralizing antibodies (see [0032] "therapeutic treatment") to anthrax (see entire document), the derived preparation being sterilized ("isolated and purified" see[0059]) and impurity free (see [0063] through [0067], especially "to a recipient mammal, preferably to a human"); and

Administering the processed plasma preparation to the infected(see [0065] through [0066]) patient (see [0064] "mammal" or "human").

Instant claim 2: "acute infectious disease" (see paragraphs [0065] through paragraph [0067]).

Instant claims 3-6: The vaccination Bacillus anthraces component is a component of the toxin, specifically "protective antigen (see title, abstract, claims 32-35).

Instant claims 9, 10,11: The plasma is derived by fractionation, specifically ion exchange chromatograph, sizing chromatograph, affinity chromatograph, hybridoma supernatants (see [0059] through [0061]).

Instant claims 12, 13, 14: The route of administration is by intramuscular, subcutaneous, parenteral injection, injectables (see paragraphs [0054 "or antibody"] through paragraph [0056]). The reference anticipates the instantly claimed invention.

8. Claim 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Little et al (1997). (ref. on USPTO-1449)

BP 6/04

Little et al discloses the instantly claimed invention directed to a method of treatment of a patient infected with anthrax using passive hyper immune antibody therapy, the method comprising the steps of:

(Instant claims 1-6): **Deriving** a supply of plasma (see materials and methods, blood comprises plasma which was processed to produce polyclonal antiserum or cells harvested for the production of monoclonal antibodies) from previously vaccinated (see guinea pigs were immunized with one of a number of anthrax antigens (see Table 1, page 5172)) individuals (see guinea pig);

Processing the plasma derived therefrom to provide a preparation (see material and methods for production of antiserum; processed plasma sample which was clotted) of gamma globulins (see monoclonal IgG1, materials and methods section; Table 1 "Concn of IgG (ug/ml)) with a high titer of neutralizing antibodies (see Table 1, neutralization activity and concentration) to anthrax (spores, whole antigen, or PA, LF, or EF components) the derived preparation being sterilized (see page 5171, col. 2, paragraph 4

adhered to the "Guide for the Care and Use of Laboratory Animals") and impurity free (see purified mAb IgG (see page 5172, col. 1, paragraph 4); and

Administering the processed plasma preparation to the infected patient (see Table 1, page 5172, col. 2 top of page "passive protection" and Fig. 2-3, page 5174) .

Inherently the reference anticipates the instantly claimed invention.

9. Claims 1-2,7-11,13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiselev et al (US Pat. 4,027,010) as evidenced by Stepanov et al (1996).

Kiselev et al (US Pat. 4,027,010) discloses the instantly claimed invention directed to a method of treatment of a patient infected with anthrax using passive hyper immune antibody therapy, the method comprising the steps of: (the recited intended use not defining over the applied prior art).

(Instant claims 1-2): **Deriving** a supply of plasma (see abstract) from previously vaccinated (see abstract paragraph 2 "blood of donors immunized") individuals (see human volunteers (see abstract paragraph 1 "human immunoglobulin);

Processing the plasma derived therefrom to provide a preparation (see title, abstract, claims) of gamma globulins (see abstract first paragraph "gamma globulin") with a high titer of neutralizing antibodies (see col. 2, lines 18-22 "three times as stronger compared with the known non-specific gamma globulins") to anthrax (Stepanov et al provides evidence that antibodies to staphylococcus surface antigens would immunoreact with anti-anthrax surface components (see page 156, col. 2, paragraph 1, second half of paragraph "antistaphylococcal and antianthrax sera block it completely. This provides strong support to the similarity of surface antigens of B.anthracis and Staphylococcus) the derived preparation being sterilized (see col. 4, line 50) and impurity free (see col. 4, lines 49-50); and

Administering the processed plasma preparation to the infected patient (see col. 2, lines 18-22 "animals have shown that the protective effect of antistaphylococcus immune globulin in staphylococcus infection") .

(Instant claim 7-8) "the plasma derived from vaccinated individuals is collected by plasmapheresis, the concentration of antibody being any amount or titer (see col. 3, lines 25-33);

(Instant claim 9) fractioned plasma to produce gamma globulin (see col. 3, lines 35-37).

(Instant claims 10-11) Cohn Fractionation; and chromatography fractionation (described by narrative language; see col. 1, lines 19-53: and col. 3, lines 35-68 and col. 4, lines 1-62; see col. 5, lines 12-48).

(Instant claims 13) intramuscular (see col. 2, lines 39-40) .

The reference inherently anticipates the instantly claimed invention in light of the evidence provided by Stepanov et al.

Conclusion

10. This is a non-final action.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Ballie et al (1999) is cited to show the distribution of IgG anti-protective antigen subclasses for anthrax antigen.

13. Fowler et al (1999) is cited to show the passive transfer of immunity and protection against anthrax in guinea pigs and SCID mice, the transfer composition comprising anti-protective antigen antibodies.

14. Casadevall (Feb. 2002) is cited to show antibodies for defense against biological attach.

15. Curry et al (US Pat. 4,719,290) is cited to show intravenous immune globulin made from large commercial pools of plasma from about 2000 donors (see detailed description, paragraph 13, starting with the phrase "native IgG").

16. Gristina et al (US Pat. 5,505,945) is cited to show compositions and methods of treating gram-positive bacterial infections with intravenous immunoglobulin.

17. Ivins et al (US Pat. 6,387,665) is cited to show a method of making a vaccine for anthrax.

18. Mangold et al (PG Pub 2002/0082386) is cited to show a claim directed to therapeutic administration of anti-anthrax antibodies to a patient (see claims 42-43 and 1-5 and entire document).
19. Maynard, JA et al (June 2002) is cited to show recombinant antibody fragments correlate wit antigen affinity and protection against anthrax toxin.
20. PG Pub 2002/0039588 Collier et al is cited to show a method of treating anthrax infection through administering antibodies specific to anthrax antigen to a patient (see claims 24-28 and entire document).
21. PG Pub 2004/0023897 Caplan is cited to show a method of treating anthrax infection with antitoxin and antibiotics (see claims 1, 15 and 16).
22. PG Pub 2003/0088074 Hamers et al is cited to show anti-anthrax antibodies for passive immunotherapy.
23. RU1347224 C (1995) is cited to show anti-anthrax hyper immune compositions that are administered subcutaneously, or intramuscularly to treat and prevent anthrax (see English abs).
24. Solokhin et al (1995, abstract only) is cited to show the use of protective antibodies contained in commercial preparations of antianthrax globulin in treatment of anthrax infected animals.
25. Stephan et al (US Pat. 4,965,068) is cited to show polyvalent hyperimmunoglobulin that comprises immunoglobulin to gram positive bacteria (see claims 5-11)

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
June 28, 2004

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600